PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
H -32407A		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/02446	10.03.2003	11.03.2002

International Patent Classification (IPC) or both national classification and IPC
A61K9/26, A61K9/26

Applicant
NOVARTIS AG

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.09.2003	15.06.2004

Name and mailing address of the international preliminary examining authority:

European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

von Eggelkraut-Gotta

Telephone No. +31 70 340-4732

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/02446

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-29	as originally filed

Claims, Numbers

8-20	received on 24.06.2003 with letter of 24.06.2003
1-7	received on 16.04.2004 with letter of 16.04.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6,7,9,15,16
	No:	Claims	1-5,8,10-14,17-20
Inventive step (IS)	Yes:	Claims	6,9,15
	No:	Claims	1-5,7-8,10-14, 16-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

V. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1: WO 97 25066 A (ASTRA AB ;DEPUI HELENE (SE); HALLGREN AGNETA (SE)) 17 July 1997 (1997-07-17)
D2: WO 01 49272 A (KERSHMAN AL ;SHEAR JEFF (US); SHEAR KERSHMAN LAB INC (US)) 12 July 2001 (2001-07-12)
D3: US-A-4 708 867 (HSIAO CHARLES H) 24 November 1987 (1987-11-24)

2 **NOVELTY** (Art. 33(2) PCT)

2.1 Document D1 discloses a tablet that comprises non-pareils having a size of 0.25 to 0.35 mm (D1, page 24, line 3). These pellets are layered with omeprazole and coated with a polymer matrix (D1, pages 22-25, example 1). The beads are sprayed with magnesium omeprazole. This core material is covered with a separating layer of a hydroxypropyl cellulose solution containing talc and magnesium stearate. Then the pellets are layered with an enteric coating and again with a hydroxypropyl methylcellulose overcoat. The layered pellets were classified by sieving. These pellets are compressed together with a granulate of excipients. The tablet comprises substrates that are supposedly comprised in the term "substrate (...) attractive to livestock and domestic animals". The term "dry feed for animals on a vegetable and / or animal basis" encompasses broadly construed also the excipients disclosed in example 1 of D1, such as potato starch.

2.2 The present application does not meet the requirements of Article 33(2) PCT because the subject-matter of claims 1-5,8,10-14,17-20 is not new.

3 **INVENTIVE STEP** (Art. 33(3) PCT)

3.1 The subject-matter of claims 1-5,8,10-14,17-20 is not new and therefore not inventive.

3.2 Dependent claims 7 and 17 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, because their subject-matter, the addition of flavours, is a matter of normal experimental design.

3.3 The subject-matter of claims 1-5,7-8,10-14, 16-20 does not to involve an inventive step as required by Article 33(3) PCT.

3.4 Dependent claims 6, 9, and 15 contain features which in combination with the features of the claims to which they refer meet the requirements of the PCT in respect to novelty and inventive step, because the prior art does not point towards benazepril as an active ingredient and lysed yeast as a substrate, in combination with the features of any claim to which they refer.

AMENDED CLAIMS

[received by the International Bureau on 25 June 2003 (25.06.03);
claims 12 and 19 added; claims 20 and 21 renumbered as claims 19 and 20;
remaining claims unchanged (2 pages)]

8. Animal medicine according to one of claims 1 to 7, characterised in that the active ingredient for veterinary medicine is an active ingredient or mixture of active ingredients, which are used against external or internal parasites, viral or bacterial diseases, behavioural disorders or dysfunction or hypo-activity.

9. Animal medicine according to claim 8, characterised in that the active substance for veterinary medicine is benazepril.

10. Process for the production of an animal medicine according to one of claims 1 to 9, characterised in that
(1) particles with an average diameter of 0.09 to 0.8 mm of a neutral-tasting, physiologically compatible, solid carrier material are coated with an active ingredient or active ingredient for veterinary medicine, so that the active ingredient encases the particles;
(2) this active ingredient casing is coated with a masking protective layer consisting of a physiologically compatible polymer matrix, which prevents direct contact of the active ingredient with the gustatory and olfactory cells and the saliva of the animal.
(3) these double-coated particles are intimately mixed with a substrate which is attractive to the animal; and
(4) the mixture consisting of substrate and double-coated particles is compressed into administrable units of an appropriate size.

11. Process according to claim 10, characterised in that the particles in stage (1) have an average diameter of 0.15 to 0.4 mm.

12. Process according to claim 10, characterised in that the particles in stage (1) consist of cellulose, starch, saccharose, lactose or sugar.

13. Process according to claim 10, characterised in that the polymer matrix in stage (2) is selected from the group consisting of: shellac, a polymer on a cellulose, acrylic acid or methacrylic acid, maleic acid anhydride, polyvinyl pyrrolidone and polyvinyl alcohol basis.

14. Process according to claim 10, characterised in that the substrate in stage (3) which is attractive to the animal is a dry feed material for animals on a vegetable and/or animal basis,

which contains optional additives, such as proteins, vitamins, minerals or artificial or natural aromatic substances.

15. Process according to claim 14, characterised in that the substrate in stage (3) which is attractive to the animal is lysed yeast.

16. Process according to claim 10, characterised in that the substrate in stage (3) which is attractive to the animal contains natural and artificial cheese, meat and fish aromas or flavour enhancers which are known from the foodstuffs industry or vanilla essence.

17. Process according to claim 10, characterised in that the active ingredient or active ingredient mixture for veterinary medicine in stage (1) is an active ingredient or mixture of active ingredients, which are used against external or internal parasites, viral or bacterial diseases, behavioural disorders or dysfunction or hypo-activity.

18. Process according to claim 10, characterised in that, in order to coat the particles in stage (1), the solid active ingredient or active ingredient mixture is dissolved in a suitable physiologically acceptable solvent or solvent mixture, applied to the particles by a spraying process and, after the spraying procedure, the solvent or solvent mixture is carefully removed.

19. Process according to claim 10, characterised in that, in order to apply the polymer matrix in stage (2), the shellac or the polymer is dissolved or dispersed in an organic solvent optionally adding water, and this solution or dispersion is sprayed by a spraying process onto the particles which are already encased by the active ingredient or active ingredient mixture, and the solvent or solvent mixture is subsequently removed under careful conditions.

20. Usage of the double-coated particles according to claim 10, produced in stage (2) for producing a veterinary medicine preparation.